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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte NATARAJAN RANGANATHAN

Appeal 2009-007490
Application 10/689,359
Technology Center 1600

Decided: March 12, 2010

Before TONI R. SCHEINER, DEMETRA J. MILLS, and
MELANIE L. McCOLLUM, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a nutritional product. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

Claims 1-10 are pending and on appeal (App. Br. 3). The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claim 1, which reads as follows:

1. A nutritional food or nutritional product for maintaining or enhancing gastrointestinal health comprising *Streptococcus thermophilus*, at least one carbohydrate ingredient at about 47% to about 82% by weight of the total weight of the nutritional food or nutritional product, at least one fat ingredient at about 2% to about 12% by weight of the total weight of the nutritional food or nutritional product, at least one protein ingredient at about 5% to about 80% by weight of the total weight of the nutritional food or nutritional product, wherein the water activity of the nutritional food or nutritional product is less than about 0.47, and wherein said nutritional food or nutritional product provides about 5 billion to 20 billion colony forming units of said *Streptococcus thermophilus* bacteria.

Claims 1-5, 7, 9, and 10 stand rejected under 35 U.S.C. § 103(a) as obvious over Paul (US 5,744,134, Apr. 28, 1998) in view of Cavaliere Vesely et al. (US 5,716,615, Feb. 10, 1998), Brassart et al. (US 5,494,664, Feb. 27, 1996), and/or Fridman (US 3,950,544, Apr. 13, 1976) (Ans. 3).

Claims 1-10 stand rejected under 35 U.S.C. § 103(a) as obvious over Paul in view of Cavaliere Vesely, Brassart, and/or Fridman, and further in view of Halpin-Dohnalek et al. (US 5,902,578, May 11, 1999) (Ans. 6).

The Examiner relies on Paul for teaching "compositions for restoring and maintaining GI health, comprising immunoglob[u]lins (protein), FOS (prebiotic), pectin (prebiotic), beneficial human intestinal microorganism[,] . . . carbohydrates such as maltodextrin and lactose, and lipids such as lecithin" (Ans. 4). The Examiner finds that Paul "clearly indicates *Streptococci* as beneficial bacteria to the GI tract" (*id.*).

In addition, the Examiner finds:

> [A]t the time of the claimed invention, *S. thermophilus* was a known and used bacteria, effective to benefit the GI tract. In support, Cavaliere Vesely teaches pharmaceutical compositions containing *S. thermophilus*, wherein the composition is effective to treat GI disorders (abstract). In addition, Brassart

> (abstract, col.3-4) and Fridman (col.3-4) both teach nutritional compositions wherein they contain microbes beneficial to the GI tract such as *S. thermophilus*.

(Ans. 5.) The Examiner concludes, therefore, that "one of ordinary skill in the art would have been motivated to use *S. thermophilus* in the composition of Paul" (*id.*).

The Examiner also finds:

> Paul teaches that the components of the composition may be varied . . . and readily determined by one of ordinary skill in the art. . . . Furthermore, the supporting references demonstrate varying amounts of the claimed components. In addition, Paul teaches the compositions may be formulated as powders . . . , suggesting a low water activity as claimed by appellant.

(*Id.*) The Examiner concludes, therefore, that "it would have been obvious to one of ordinary skill in the art to optimize the amounts of components and water content of the composition of the cited reference with a reasonable expectation for successfully obtaining the reference composition" (*id.*).

The Examiner relies on Halpin-Dohnalek for teaching a nutritional composition that comprises minerals and vitamins (*id.* at 7-8), as recited in claims 6 and 8.

ISSUES

Does the evidence support the Examiner's conclusion that it would have been obvious to provide 5 to 20 billion colony forming units of the *Streptococcus thermophilus* bacteria?

Does the evidence support the Examiner's conclusion that it would have been obvious to include at least one fat ingredient at about 2% to about 12% by weight of the total weight of the composition?

Does the evidence support the Examiner's conclusion that it would have been obvious to form a composition having a water activity of less than about 0.47?

FINDINGS OF FACT

1. Paul discloses "an immunoglobulin and fiber-containing composition for use as a dietary supplement for restoring and maintaining gastrointestinal health" (Paul, col. 3, ll. 60-62).

2. Paul also discloses that the "composition can also include a carrier" and that a "preferred carrier comprises at least one member selected from the group consisting of a carbohydrate and a lipid," a preferred lipid being lecithin (*id.* at col. 4, ll. 30-37).

3. In particular, Paul discloses an immunoglobulin composition containing "(1) about 55-60 parts by weight of an immunoglobulin concentrate . . . , (2) about 35-40 parts by weight of a mixture of carbohydrates . . . , and (3) about 5-10 parts by weight of lipid including lecithin" (*id.* at col. 5, ll. 32-45).

4. Paul also discloses:

> Certain bacteria have . . . been shown to be beneficial to human gastrointestinal health. The intestinal flora of the human gut contains some $100x10^9$ viable bacteria, representing 100 or more different species. The major bacteria can be roughly divided into three groups: (a) lactic acid bacteria, including lactobacilli, bifidobacteria, and streptococci; (b) anaerobic bacteria; and (c) aerobic bacteria.

(*Id.* at col. 9, ll. 44-50.)

5. In addition, Paul discloses that its "composition can optionally contain one or more of a beneficial human intestinal microorganism" (*id.* at Abstract). In particular, Paul discloses:

> It is . . . preferable that the formulation contain a beneficial human intestinal microorganism for restoring and maintaining good gastrointestinal health. The beneficial human intestinal microorganism is preferably a member selected from the group consisting of lactobacilli and bifidobacteria. . . . Such beneficial human intestinal bacteria can be added to the base formulation in an amount in the range of about 0 to about 20% by weight.

(*Id.* at col. 13, ll. 17-32.)

6. Paul also discloses that the "composition is preferably manufactured in powder form" (*id.* at col. 13, ll. 62-63).

7. Cavaliere Vesely discloses a "pharmaceutical composition containing several different bacteria including *Streptococcus thermophilus*, Lactobacilli and Bifidobacteria" (Cavaliere Vesely, Abstract).

8. Cavaliere Vesely also discloses using the pharmaceutical composition to treat a gastrointestinal disorder (*id.*).

9. In addition, Cavaliere Vesely discloses that the "bacteria are present in the composition at a total concentration of $1x10^{11}$ to $1x10^{13}$ per gram" (*id.*).

10. Cavaliere Vesely also discloses a preferred composition containing "31% by weight of lyophilized *Streptococcus thermophilus*, $7x10^{11}$" (*id.* at col. 3, ll. 1-3).

PRINCIPLES OF LAW

"[W]here there is a range disclosed in the prior art, and the claimed invention falls within that range, there is a presumption of obviousness."

Iron Grip Barbell Co., Inc. v. USA Sports, Inc., 392 F.3d 1317, 1322 (Fed. Cir. 2004). However, it may be possible to rebut this presumption "if it can be shown: (1) That the prior art taught away from the claimed invention, *In re Geisler*, 116 F.3d 1465, 1471 (Fed.Cir.1997); or (2) that there are new and unexpected results relative to the prior art, *In re Woodruff*, 919 F.2d 1575, 1578 (Fed.Cir.1990)." *Id.*

ANALYSIS

Paul discloses a nutritional product for restoring and maintaining gastrointestinal health, comprising protein, carbohydrate, and fat (Findings of Fact (FF) 1-3). Paul also discloses that the composition may additionally comprise one or more beneficial human intestinal microorganisms (FF 5). Paul discloses that the beneficial human intestinal microorganism is preferably lactobacilli or bifidobacteria (FF 5). However, in addition to lactobacilli and bifidobacteria, Paul discloses that streptococci are major intestinal lactic acid bacteria of the human gut (FF 4).

Cavaliere Vesely discloses a composition for treating a gastrointestinal disorder comprising *Streptococcus thermophilus*, as well as Lactobacilli and Bifidobacteria (FF 7-8). Based on this disclosure, we agree with the Examiner that it would have been prima facie obvious to include *Streptococcus thermophilus* in Paul's nutritional product.

Appellant argues, however, that "Paul does not disclose any fact or notion for providing a high titer (*e.g.*, 5 to 20 billion CFU) of a viable probiotic, in particular *S. thermophilus*, to the gastrointestinal tract" (App. Br. 11-12). Instead, Appellant argues that probiotics are optional (*id.* at 12). Accordingly, Appellant argues that "Paul provides no recognition that

probiotics at particular titers are essential to achieve the result of restoring or maintaining gastrointestinal health" (*id.*). In contrast, Appellant argues:

> Applicant has appreciated that a food or nutritional product containing a high titer of probiotic bacteria, ranging from about 5 to 20 billion CFU's, provides not only good gastrointestinal health and overall well-being, but also a greater propensity to hydrolyze toxic nitrogenous waste products thereby alleviating symptoms of uremia. See page 13, lines 23-28.

(App. Br. 12.)

Appellant also argues that "the secondary references . . . fail to overcome the deficiencies of Paul" (*id.* at 13). In particular, Appellant argues:

> Although *S. thermophilus* is mentioned by Cavaliere Vesely et al., nowhere does this patent teach or suggest 5 to 20 billion colony forming units of *S. thermophilus* in a composition. In fact, Cavaliere Vesely et al. specifically teach use of a much higher titer, namely 7 x 10^{11} colony forming units of bacteria, or at least 100 billion colony forming units.

(*Id.*)

We are not persuaded. Paul discloses that "beneficial human intestinal bacteria can be added to the base formulation in an amount in the range of about 0 to about 20% by weight" (FF 5). It is undisputed that this broad disclosure encompasses compositions that provide about 5 billion to 20 billion colony forming units of *Streptococcus thermophilus*.[1] Thus, there

[1] In this regard, we note that claim 1 does not require a number of colony forming units per gram (cfu/g). Thus, even a composition with fewer than 5 billon cfu/g could meet the claimed range if the composition is larger than one gram.

is a presumption of obviousness. *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, *supra*.

Although Cavaliere Vesely discloses compositions comprising a relatively high amount of *Streptococcus thermophilus* (FF 9-10), Appellant has not shown that Cavaliere Vesely teaches away from the claimed amounts. In addition, Appellant has not provided sufficient evidence that the claimed amounts provide unexpectedly superior results. Thus, Appellant has not overcome the Examiner's prima facie case of obviousness.

Appellant additionally argues:

> [T]he claimed low-moisture nutritional food or nutritional products are an improvement over existing probiotic compositions, which are "prone to loss in viability due to their greater susceptibility to moisture, light, oxygen and heat," (see page 14, lines 15-24) in that the claimed compositions provide various elements which ensure a long shelf life and a viable population of probiotic bacteria. For example, the specification teaches that not only does the fat ingredient function as a lubricant, it also acts as a moisture barrier which has the "added benefit of protecting the probiotic bacteria from moisture, which is detrimental to maintaining a viable population of bacteria." See page 17, lines 4-8. In this regard, the claims clearly provide for a fat ingredient and further specify a water activity of less than about 0.47.[2]

(App. Br. 12.)

We are not persuaded. Paul discloses that its "composition is preferably manufactured in powder form" (FF 6). Appellant has not

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[2] We note that neither claim 9 nor claim 10 requires a composition comprising a fat. In addition, claim 10 does not require a composition having a water activity of less than about 0.47. Thus, this argument does not apply in whole to claim 10 and in part to claim 9.

provided sufficient reasoning or evidence to rebut the Examiner's conclusion that a powder would have a low water activity, such that a water activity of less than about 0.47 would have been obvious (Ans. 5).

In addition, Paul discloses including fat in its composition (FF 2). In particular, Paul discloses an immunoglobulin composition containing "(1) about 55-60 parts by weight of an immunoglobulin concentrate . . . , (2) about 35-40 parts by weight of a mixture of carbohydrates . . . , and (3) about 5-10 parts by weight of lipid including lecithin" (FF 3). Although this teaching does not recite that the final composition[3] has a fat content of about 5-10 parts by weight, we agree that this teaching renders obvious compositions having a fat content recited in claim 1.

With regard to the rejection that includes Halpin-Dohnalek, Appellant argues that Halpin-Dohnalek fails to compensate for the deficiencies in Paul (App Br. 16). In particular, Appellant argues that "[n]owhere does this reference teach or suggest the claimed amounts of ingredients, *e.g.*, the claimed fat content, or water activity, which are specified in the present claims to preserve bacterial titer" (*id.*). Given that we are not persuaded by Appellant's argument that Paul does not suggest these features, we are not relying on Halpin-Dohnalek to compensate for these alleged deficiencies.

CONCLUSION

The evidence supports the Examiner's conclusion that it would have been obvious to provide 5 to 20 billion colony forming units of the *Streptococcus thermophilus* bacteria. The evidence also supports the

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[3] Paul discloses that its composition comprises about 40 to about 60% of an immunoglobulin composition (Paul, col. 3, ll. 60-65).

Examiner's conclusion that it would have been obvious to include at least one fat ingredient at about 2% to about 12% by weight of the total weight of the composition. In addition, the evidence supports the Examiner's conclusion that it would have been obvious to form a composition having a water activity of less than about 0.47. Thus, we affirm the obviousness rejections of claim 1 over Paul in view of Cavaliere Vesely, Brassart, and/or Fridman, with and without Halpin-Dohnalek. Claims 2-10 fall with claim 1.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc

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